BREAST PROSTHESIS

Sub B1 ~~The invention relates to an implantable breast prosthesis adapted more particularly to breast augmentation surgery and breast reconstructive surgery.~~

Breast prostheses are generally constituted of a silicone-type elastomeric soft pouch which is filled with a more or less viscous fluid. In Europe, this fluid most often is a physiological serum-base fluid which is inserted into the pouch during implantation of the prosthesis through an appropriate opening in the pouch which is sealed after the filling. In the United States, in particular, silicone gels are also used, inserted into the pouch which is then sealed before implantation. A particular type of prosthesis is called an expander: these prostheses are implanted beneath the area of the tissues to be expanded, then are progressively filled by an appropriate valve system with a fluid such as a physiological serum. Several examples of embodiment of these conventional or expansion prostheses are found in the Patent Applications FR-2 735 354, FR-2 726 173, and FR-2 677 539.

Numerous prostheses are currently commercially available, these prostheses having so-called "high profile," "low profile", or "anatomical" round shapes. All of them attempt as close an approximation to the natural shape of the breast as possible, but none has fully succeeded. The round-shaped prostheses do not feel natural, are overly projecting in the upper and inner parts (in a known fashion, the volume of the breast, as well as that of the prosthesis can be resolved into four parts depending upon their position in relation to the bust). With respect to the so-called anatomical shape, they have a more adapted shape, but they can easily be positioned incorrectly within the surgical pocket, because their posterior surfaces (i.e., the area of the prosthesis to be placed in contact with the thorax, which is also called the placement) have an inadequate contact with the thorax.

Sub B2 ~~An object of the present invention is an improvement to the design of breast~~ prostheses, this improvement aiming particularly at a more aesthetic aspect, which is closer to that of the natural breast, regardless of whether the person wearing the prosthesis is seating, standing, or laying down, and/or a greater ease in positioning the prosthesis correctly during implantation, and/or a more constant retention of the prosthesis once it is implanted in the correct position, and/or a greater comfort in wearing the prosthesis.

A primary object of the invention is a breast prosthesis comprising a soft pouch capable of containing a sufficiently fluid filling material, such as a silicone or hydrocolloid ~~gel or a physiological serum, said prosthesis being made side-specific.~~

In the context of the invention, "made side-specific" means that, once filled, the

pouch demarcates a volume that cannot be placed indifferently to the left or to the right on the person's thorax: therefore, one obtains a right prosthesis and a left prosthesis, which are as specific as the natural breasts, especially with respect to the geometry of the posterior surface of the pouch and/or that of the anterior surface thereof ("anterior", as opposed to "posterior," designates the surface created by the pouch turned to the side opposite the thorax).

In addition to this side-specific arrangement translating into differences in the geometry between the (lower and upper) outer parts, on the one hand, and the (lower and upper) inner parts on the other hand, one can advantageously provide an additional side-specific arrangement translating into differences in the geometry between the (inner and outer) lower parts, on the one hand, and the (inner and outer) upper parts on the other hand: thus, one can also distinguish, in each prosthesis of the invention, the "upper" portion and the "lower" portion, in the implantation position, which cannot be inverted.

In the context of the invention, a "pouch capable of containing" means either the complete prosthesis, with the pouch fully filled with the filling fluid, or the partially filled pouch, or yet the pouch still empty since, as mentioned hereinabove, the protheses, depending particularly on the type of filling fluid selected or the function of the prosthesis, are in the form of empty or pre-filled pouches before implantation. Preferably, it is a final prosthesis. Since the geometry of the pouch determines that of the prosthesis as a whole, once the pouch is filled, the invention is more clearly defined with reference to a filled pouch defining the volume approximating that of the breast.

Indeed, the inventors became aware that such a "side-specific arrangement", such an asymmetry was the solution to the problem of overcoming the disadvantages of the prostheses currently used.

Sub B3 ~~This side-specific arrangement can be obtained at various levels, which can be alternative, or preferably cumulative.~~

Thus, a first level is the choice of an asymmetry of the pouch in the implantation position (for ease of understanding, the implantation position is that of a person standing or sitting with her bust straight), once filled, in relation to a plane P1 passing by the nipple E (the front pole of the anterior surface simulating the breast nipple) and by the lower D and upper B front edges. Thus, this characteristic takes into account the asymmetry of the breasts in relation to a vertical sagittal plane. Indeed, a natural breast is hemispherical only on a teenager. Subsequently, it spreads on the thorax wall and then progressively displays a more rounded and more protruding aspect in the lower and outer parts. The asymmetry

according to the invention advantageously enables the volume of the lower outer part of the implanted prosthesis to be larger than that of the lower inner part and/or that of the upper outer part to be larger than that of the upper inner part.

Sub B4 ~~Preferably, this asymmetry is defined by a difference in the dimensions between the~~ projection of the distance EC between the nipple and the front inner edge, on the one hand, and the projection of the distance EA between said nipple and the front outer edge, on the other hand, the projections being made along a plane P2 perpendicular to the plane P1 passing by the aforementioned nipple and containing said nipple E as well as the front upper edge B. The ratio between these two projections is advantageously less than or equal to 0.95, especially comprised between 0.8 and 0.9, or between 0.85 and 0.90. The preferred embodiment consists of selecting a ratio on the order of 0.875, which is that most capable of reproducing the more outwardly projecting aspect of the natural breast, whereas the ~~currently available prostheses have a ratio strictly equal to 1.~~

Conversely, it is preferable that the projection of the distance EC between the nipple E and the inner edge C be equal to or very close to the projection of the distance EA' between the nipple E and the rear outer edge A', along this same plane P2: this configuration especially allows obtaining an outer "overlap" of the filled pouch in the implantation position in relation to the posterior surface thereof, this overlap extending in particular between the lower D and upper B rear edges, which simulates the aspect of the natural breast at best.

Advantageously, the prosthesis is designed such that, along the plane P2 described hereinabove, the dimension of the projection of the distance BE between the upper edge B and the nipple E is greater than the dimension of the projection of the distance ED between the nipple and the lower edge D. The ratio r (BE/ED) is preferably at least 1.1, especially between 1.1. and 2, or between 1.3 and 1.5.

Incidentally, to obtain the aforementioned "outward" overlapping effect, it is advantageous to have the plane P5 tangent, at k (the rear outer edge) to the anterior surface of the prosthesis form, at k, with the plane P6 tangent, at said point k, to the posterior surface, an obtuse angle ϕ, especially greater than 95 or 100°, in particular comprised between 91° and 120°, for example on the order of 115°.

Preferably, the prosthesis does not contain any axillary extension or the like.

A second level of side-specific arrangement relates to taking into account the natural convexity of the thorax in a horizontal plane (still with the understanding that the prosthesis is filled and in the implantation position). The current prostheses have a planar posterior

surface. The incorrect positions, prosthetic rotations and aesthetic drawbacks observed after implantation are explained in particular by this choice: since the prostheses assume the shape of the thoracic plane only on an insufficient surface, they can easily move. Conversely, according to the invention, at least one concave curvature is preferably imparted to the posterior surface, in order to increase this contact surface, and therefore to improve the fit of the prosthesis on the thorax.

Advantageously, a first concave curvature is provided in a horizontal plane P3, this plane passing by the inner edge C, for example. In this case, the perpendicular projection GG' of the pole G of the posterior surface on the horizontal plane P4 containing the outer rear edge A' and the inner edge C, is at least 3 mm, especially at least 5 mm or 1 cm, for example 0.8 - 1.5 cm.

Still advantageously, the posterior surface can also have a concave curvature, in a vertical plane P9, this time, this vertical plane passing by the upper edge B, for example. In this case, the perpendicular projection HH' of the pole H of the posterior surface along this curvature on a vertical plane P10, perpendicular to P9 and passing by the upper edge B, is at least 2 mm, especially comprised between 3 and 6 mm.

It is with this double curvature that the posterior surface closely fits the curvature of the thorax at best. Advantageously, the first curvature is uninterrupted between the inner edge C and the outer rear edge A', and similarly, the second curvature is uninterrupted from the upper edge B to the rear lower edge D (i.e., with no inverted planar or curvature zone between the two points considered for each of the curvatures).

To obtain this non-planar posterior surface, it can be made more rigid, less deformable than the anterior surface, for example by selectively increasing the thickness of the wall of this surface.

A third level of side-specific arrangement relates to the "connection" zones between the prosthesis and the thorax: the completely symmetrical prostheses currently available generally do not take into account either that the natural breasts, especially in the inner zone and in the upper zone, connect to the thorax along a "gentle" slope and not in a quasi-perpendicular manner with respect to the thorax.

Conversely, according to the invention, one first provides to simulate this gentle slope connection in the upper zone of the prosthesis, by designing the prosthesis such that the planes P10 and P11 tangent to the posterior surface and to the anterior surface, respectively, of the pouch, once it is filled and in the implantation position at the upper edge B, form therebetween an angle less than or equal to 70°, especially less than or equal to 65

or 60°, for example on the order of 40°.

Alternatively or cumulatively, the invention also provides a gentle slope connection of the prosthesis with the thorax in the inner zone of the prosthesis: the pouch is designed such that the planes P7 and P8 tangent to the anterior surface and to the posterior surface, respectively, of the pouch, once it is filled and in the implantation position at the inner edge C, form therebetween an angle less than or equal to 70°, especially less than or equal to 65 or 60°, for example on the order of 40°.

Sub B5 ~~The object of the invention concerns the protheses having at least one level of side-~~ specific arrangement and pertaining to the family of prostheses defined in the preamble of the present application. It relates to prostheses having all of the volumes commonly used in breast surgery, namely, prostheses which, once filled, have a volume ranging from 80 cm^3 to 700 cm^3.

The details and advantageous characteristics of the invention will now become apparent from the following non-limiting example, by means of Figures 1-6:

- Figure 1 schematically shows a transverse cross-section of a thorax with natural breasts.
- Figure 2 shows the same cross-section with two prostheses according to the prior art.
- Figure 3 shows the same cross-section with two prostheses according to the invention.
- Figure 4 shows a view of the anterior surface along a vertical plane of the right prosthesis according to the invention.
- Figure 5 shows a view of the prosthesis of Figure 4 in a horizontal cross-section.
- Figure 6 shows a side view of the prosthesis of Figure 4.

Therefore, Figure 1 is a transverse cross-section of the thorax in a mediastinal window passing by the fourth dorsal vertebra, schematically shown from a scannographic illustration. One sees the spine 10, the two breasts 11 and 12, the mediastinum 13, the lung fields 14 and 15, the costal plane 16. It can be noted that the two breasts "spread" naturally on the thoracic plane 16 by assuming its convex shape. The arrows represent the inner and outer limits of the projection of the two areolar glands on the thorax.

Figure 2 shows, along the same cross-section as in Figure 1, some of the drawbacks of one type of (comparative) prosthesis that is currently commercially available: the prostheses 21 and 22 have planar posterior surfaces 23 and 24 which do not follow the curvature of the thorax. In addition, they create, in the inner zones 25 and 26 for connection ~~with the thorax, an almost 90° angle with said thorax. And we are almost in the same~~

Sub B5

~~situation in the outer connection zones 27 and 28: the external appearance of the prosthesis~~ is therefore anaesthetic, on the one hand, and it is susceptible of moving in the pocket where it is implanted, increasing the anaesthetic effect and the discomfort for the person, on the other hand.

Figure 3 shows the prostheses 31, 32 according to a preferred embodiment of the invention: they are much closer to the aspect of the breasts of Figure 1, with a posterior surface 33, 34 assuming the convexity of the thorax as closely as possible, and connections in inner zones 35, 36 and in outer zones 37, 38 along a gentle slope. The prostheses 31, 32 have a volume that is better distributed and closer to the thoracic cage; as a result, they are much less susceptible of moving. It is also seen that the prostheses 31, 32, contrary to the prostheses 21, 22, are not interchangeable. They are made side-specific, asymmetrical as are the natural breasts.

The following Figures will discuss the geometry of the prosthesis 31 in detail.

Figure 4 therefore shows a front view of the right prosthesis 31 of Figure 3. It is understood that from this representation, as well as all of the following ones, can derive those of the left breast, which is the mirror construction in volume of the right prosthesis. ~~This representation and the following ones are on a scale of 1.~~

The point E shown is the front pole of the prosthesis, which corresponds to the nipple of the natural breast, the point C is the inner edge (that which is going to be turned toward the other prosthesis in the implantation position), the points B and D are the upper and lower front edges, respectively, the point A is the front outer edge (as opposed to "inner"), the point A' is the rear outer edge and the point D' the rear lower edge. This is a prosthesis having a volume of about 480 cm^3.

Sub B6

~~The dimensions of the distances between these various points, measured in the plan~~ P2, are as follows:

AA' = 1 cm (length of the outer overlap)
A'C = 14 cm (base of the prosthesis)
AC = 15 cm (total width of the prosthesis)
BD = 12 cm (total height of the prosthesis)
DD' = 2 mm
A'E = EC = 7 cm
AE = 8 cm
BE = 7 cm
~~ED = 5 cm~~

It is seen that the prosthesis does not have any symmetry in relation to the plane P1 passing by B, D, and E, and perpendicular to the plane P2 represented in the Figure: the distance EC is notably shorter than the distance AE, and the volumes of the upper 40 and lower 42 outer parts are larger than that of the volumes of the upper 41 and lower 43 inner parts. There is a hatched area 44 that corresponds to an overlap of the anterior surface in relation to the surface developed by the posterior surface, which translates into the distance separating the points A and A'. This overlap is most substantial in the vicinity of the points A and A', but it is seen that it extends up into the inner lower part 43 (the distance between D and D' is not negligible). The prosthesis also has an asymmetry between the volumes of the lower 42 and upper 40 outer parts, on the one hand, and between the volumes of the lower 43 and upper 41 inner parts, on the other hand, which translates into the difference between the distances BE and ED. In the present case, the ratio r (BE/ED) is 1.4. This ratio can be generally selected preferably between 1.1 and 2, especially between 1.3 and 1.5.

Figure 5 is a horizontal cross-sectional view of the previous Figure. According to this cross-section, the point F is the pole of the anterior surface 52 and G the pole of the posterior surface 51. G' is the projection of G in the plane P4 which is the plane perpendicular to the plane of the cross-section, and which passes by k and C. It must be noted that the axes BD of Figure 4 and FG of this Figure are perpendicular to one another, but with an offcentering of about 1 cm. They do not intersect.

The distances between these various points are:

GG' = 1.3 cm

FG = 5 cm (front projection of the prosthesis)

kG' = 6 cm

GC = 8 cm

Sub B7 ~~Therefore, one easily sees that the posterior surface 51 has a uniform concavity extending between the points k and C. This concavity can be quantified by the distance GG' which is greater than 1 cm, and by the angles α formed by the planes tangent to the posterior surface 51, at points k and C, with the plane P4. Here, the two angles on the outer and inner side are substantially identical (about 25°, which can be comprised between 20° and 30°), but it could be otherwise. It can be noted that G' is not in the middle of kC. There is an A'G/G'C ratio of about 0.75 (for example comprised between 0.5 and 1). The hatched area 53 corresponds to the outer overlap designated by the reference numeral 44 in the previous Figure; it makes it possible to see more clearly that the prosthesis allows obtaining the natural effect of an outwardly projecting breast.~~

Sub B7 ~~Figure 5 also makes it possible to show a gentle slope connection mentioned~~ hereinabove, the connection between the inner edge C of the prosthesis and the thorax: thus, the plane tangent to the posterior surface 51 at point C forms, together with the plane tangent to the anterior surface at same point C, a small angle β, much less than 90°, here on the order of 40°.

Figure 5 also shows that the outer overlap also translates into an angle ϕ of about 115°, at k, between the plane P5 passing by k and tangent to the anterior surface 52 and the ~~plane P6 also passing by k and tangent to the posterior surface 51 of the prosthesis.~~

Figure 6 is a side view of the prosthesis 31. The point I is the pole of the anterior surface 52 along the plane of the Figure. The point H is the pole of the posterior surface 51 along the plane of the Figure. The point H' is the perpendicular projection of H on a vertical plane P9 passing by B and perpendicular to the plane of the Figure. The distances between these various points are as follows:

HH' = 3.5 mm

HI = 5 cm (front projection of the prosthesis)

HD = 5 cm

H'B = 7 cm

DD' = 2 mm

Sub B8 ~~The posterior surface 51 has a second concavity in the plane of the Figure. This~~ concavity can be quantified by the distance HH' which is greater than 1 mm, and by the angles χ formed by the plane tangent to the posterior surface 51 at point B with the plane P9. (The situation is the same at point D', the concavity extending from B up to D'). Here, the angle χ is about 7°, and can be comprised between 4° and 15°, for example.

Figure 6 also makes it possible to see a second gentle slope connection on the upper zone of the prosthesis: at point B, the angle δ formed by the plane P10 explained hereinabove and the plane P11 tangent to the anterior surface to point B is small, much less ~~than 90° or 60°, and it is selected here to be about 38.5°.~~

The distance HI is an important characteristic of the prosthesis because it makes it possible to define the front projection of the prosthesis. In this specific example, it is 5 centimeters, but it can be selected more generally in a range of 3-7 centimeters.

Sub B9 ~~In conclusion, this non-limiting example of prosthesis is the one that combines all~~ of the characteristics of the invention for even closer an approximation to the aspect of the natural breast than before. Prostheses of various volumes can result from mere similarity. ~~However, it remains consistent with the invention to provide prostheses that would not~~

Sub B9

~~cumulate all of the means for side-specific arrangement, (adaptation to the convexity of the~~ thorax by a concave posterior surface ~~and~~/or at least one “gentle slope connection”, and/or an asymmetry ~~in~~ relation to a vertical plane passing by the nipple, and/or an outer ~~“overlap”~~ ...).